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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,608	01/14/2002	Leonard Bell	ALXN-P01-059	5748

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EXAMINER	
VANDERVEGT, FRANCOIS P	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/047,608	BELL, LEONARD	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-32 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-30 and 34* is/are rejected.

7)☒ Claim(s) *31 and 32* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application claims the benefit of the filing date of provisional application 60/262,540.

Claims 1-26, 33 and 35-41 have been canceled.

Claims 27-32 and 34 are currently pending and are the subject of examination in the present Office Action.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 23, 2006 has been entered.

In view of Applicant's amendments filed February 23, 2006, no outstanding ground of rejection is maintained.

The following represent new grounds of rejection.

Applicant's arguments with respect to claims 27-32 and 34 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 27-30 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. (See Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, especially page 1106 3rd column). A "representative number of species" means that the species that are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. MPEP 2163 II.A.3a.ii.

The claims are broadly drawn to the use of any anti-inflammatory agent for a method of prophylaxis against a myocardial infarction in a patient undergoing cardiopulmonary bypass surgery by administering the anti-inflammatory agent to the patient as a bolus at or before the start of surgery as well as administering an additional subsequent amount of the anti-inflammatory agent. The specification lists a number of anti-inflammatory agents directed at a variety of *in vivo* targets (pages 5 and 11 of the specification, for example). However, the disclosure is only directed to a preferred embodiment and exemplification of anti-inflammatory agents directed against a single component of the complement pathways. Applicant's disclosure has provided no demonstrative evidence that anti-inflammatory agents directed against other targets (e.g., COX-1 or COX-2, as listed on page 5) would be operative in treating the inflammatory response associated with myocardial infarction. Furthermore, among those agents that target the complement pathways, the only agent that is exemplified in the specification is the monoclonal antibody 5G1.1 as the humanized recombinant fragment h5G1.1-scFv. This mAb is directed at complement component C5 and blocks the conversion of C5 into the C5a anaphylatoxin and C5b fragments. C5a anaphylatoxin is well known in the art to be a strong inflammatory agent. However, based upon the instant disclosure it is not clear whether the effect of the exemplified h5G1.1-scFv agent is due to the prevention of anaphylatoxin activity or prevention of the progression of the complement cascade through C5b to the $C5b678(9)_n$ complex. If the inflammatory response being prevented by the claimed method is due solely to the action of C5a, then agents, such as antibodies, specific for complement components C6, C7, C8 and C9 would be ineffective. It would be apparent to the artisan, however, that the exemplified h5G1.1-scFv agent would not be acting on inflammatory stimuli outside of the complement cascade. Additionally, there is no disclosure as to whether the inflammatory response being prevented is due to the action of the classical pathway or the alternative pathway of complement

activation. It is well established in the art that the two complement activation pathways converge at the point of C3 cleavage into C3a and C3b and that C3b is a component of complexes that participate in the cleavage of C5. However, if the inflammatory response being inhibited in the instantly claimed method is due to the activation of the classical pathway, then agents, such as antibodies, against alternative pathway elements, such as Factors B, P and D for example, will be ineffective. Conversely, if the inflammatory response being inhibited in the instantly claimed method is due to the activation of the alternative pathway, then agents, such as antibodies, against classical pathway elements, such as C1, C2 and C4 will be ineffective.

Accordingly, the only species of anti-inflammatory agent that has been adequately described in the specification for use in the instantly claimed method is an antibody against C5 that prevents conversion of C5 into C5a and C5b. The agent exemplified in the instant specification acts solely in this role and there is no description, other than a listing of potential targets, of other inflammatory elements that are affected by the action of an anti-inflammatory agent in the practice of the claimed method. Accordingly, the humanized recombinant fragment h5G1.1-scFv cannot be relied upon as being descriptive of anti-inflammatory agents other than antibodies that prevent conversion of C5 into C5a and C5b. There is no evidence that any other anti-inflammatory agent suitable for use in the claimed method was in Applicant's possession at the time the invention was made.

Vas-Cath Inc. v. Mahurkar ((CAFC, 1991) 19 USPQ2d 1111) clearly states that "Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See *Vas-Cath* at page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see *Vas-Cath* at page 1115).

Allowable Subject Matter

3. Claims 31 and 32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
June 9, 2006

DAVID SAUNDERS
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